



NDA 50-655/S-013

Baxter Healthcare Corporation
Attention: Marcia Marconi
Vice President, Regulatory Affairs
Route 120 and Wilson Road
Round Lake, Illinois 60073-0490

Dear Ms. Marconi:

Please refer to your supplemental new drug application dated August 27, 2002, received August 28, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nallpen[®] (nafcillin sodium injection) in Plastic Container, PL 2040. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental new drug application responds to the labeling revisions suggested by the Agency in the not approvable letter, dated July 17, 2000.

We have completed the review of this supplemental application. This application is approved, effective on the date of this letter for use as recommended in the agreed-upon labeling text, submitted August 27, 2002.

Please submit the copy of final printed labeling (FPL) electronically according to the Guidance for Industry titled "Providing Regulatory Submissions in Electronic Format – NDA". Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-655/S-013." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

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If a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Susmita Samanta, M.D., Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Janice Soreth
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